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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC **PLAINTIFFS' RESPONSE TO BARD'S MOTION TO EXCLUDE THE OPINIONS OF ROBERT M. McMEEKING, PH.D.**

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Robert M. McMeeking, Ph.D. ("Motion" or "Mot.") [Doc. 7314]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Dr. McMeeking is well qualified and his testimony and opinions are admissible under *Daubert*[1] and its progeny. Dr. McMeeking is an experienced Professor of Mechanical Engineering and Materials Science who employed reliable methodology using standard, well-accepted methods of his discipline to reach design defect opinions that will be helpful to the jury. Utilizing his extensive education, knowledge, training, and

[1] *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

experience, Dr. McMeeking reached his expert opinions by performing analytical mathematical calculations, by modeling the performance of Bard's IVC filters using Finite Element Analysis (FEA), and by reviewing thousands of pages of Bard documents and deposition testimony regarding the design, testing, and manufacture of Bard's IVC filters. Defendants' Motion, which is riddled with misstatements regarding Dr. McMeeking's opinions, should be denied in light of Dr. McMeeking's expertise and based upon the relevance and reliability of his opinions, as set forth below.[2]

II. DR. McMEEKING IS QUALIFIED TO OFFER HIS OPINIONS.

Dr. Robert M. McMeeking is a mechanical engineer and materials scientist. He holds a Bachelor of Science degree in mechanical engineering (1st Class Honours) from the University of Glasgow and both a Master of Science and a Doctorate in Engineering from Brown University.[3] He is currently the Tony Evans Professor of Structural Materials and Distinguished Professor of Mechanical Engineering at the Engineering Department of the University of California, Santa Barbara. (Def. Ex. A, McMeeking 3/3/17 Report, at 1.) Dr. McMeeking has taught mechanical engineering and materials science to undergraduate and graduate engineering students for more than forty (40) years. (*Id*.) He teaches classes in mechanical engineering design and analysis "to equip students with the knowledge and understanding required to carry out the processes necessary to conceptualize, design, analyze and manufacture engineering products." (*Id*.)

Dr. McMeeking has been elected to two prestigious and highly selective engineering bodies and to a prestigious academy of distinguished scholars: he is a member of the U.S. National Academy of Engineering and a Fellow of both the U.K. Royal Academy of Engineering and the Royal Society of Edinburgh. (*Id*.) He is also a Life Fellow of the American Society of Mechanical Engineers, a status accorded to only senior members with high achievements in mechanical engineering, and a recent recipient of the

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[2] For a discussion of *Daubert* and Rule 702 standards, Plaintiffs incorporate and refer the Court to Section I of Plaintiffs' Omnibus Memorandum.

[3] Dr. McMeeking's curriculum vitae is attached as an appendix to his March 3, 2017 report, and is Exhibit 1 to this response.

Timoshenko Medal of the American Society of Mechanical Engineers, the highest recognition and prize awarded to mechanical engineers engaged in solid mechanics and stress analysis. (*Id*.) Dr. McMeeking served a full ten-year term as Editor of the American Society of Mechanical Engineers' Journal of Applied Mechanics, finishing in 2012. (*Id*.) The American Society of Mechanical Engineers is the leading U.S. professional society concerned with mechanical (stress/strain) analysis, and the Journal of Applied Mechanics is its leading professional publication addressing the mechanical behavior of solids. (*Id*.)

Dr. McMeeking has significant experience related to biomedical implants. For over forty-five years, Dr. McMeeking has "performed extensive research into problems of mechanical failure in a wide range of structural components, including biomedical implants." (*Id*.) He has a particular expertise – which he brought to bear in this case – in the analysis of mechanical, structural, and materials behavior and their implications for fracture, fatigue, tissue penetration, and implant stability. (*Id*.) Dr. McMeeking has testified both formally and informally before the U.S. Food and Drug Administration (FDA) regarding his engineering assessments of medical implants, including issues pertaining to *in vivo* loading, stress/strain analysis, fatigue, fracture, stability, and durability. (*Id*. at 1-2.) In addition, Dr. McMeeking has served as a paid outside consultant to multiple leading medical device companies. (*Id*. at 1-2.) In this role, he has provided analyses and advice on the functionality, design, reliability, and manufacturing of a broad range of devices, including heart valves, stents, and other biomedical implants. (*Id*. at 1.)

In summary, Dr. McMeeking is qualified by his education, training, and experience to render technical opinions concerning the design of Bard's IVC filters. *See Tillman v. C.R. Bard., Inc.*, 96 F. Supp. 3d 1307, 1324 (M.D. Fla. 2015) (finding Dr. McMeeking "qualified to opine on mechanical failure and stress-strain analysis" of Bard's IVC filters).

III. ARGUMENT

A. Dr. McMeeking's Opinions Regarding Bard's Failure to Reduce the Risks Associated with its Filters are Reliable.

Bard first argues that this Court should preclude Dr. McMeeking from testifying regarding Bard's failure to go far enough to reduce the risks of its filters. (Mot. at 4-7.) But, Bard repeatedly misstates Dr. McMeeking's deposition testimony and ignores the entirety of Dr. McMeeking's Rule 26 Reports, which comprehensively address how and why "Bard did not go far enough to reduce the risks associated with its filters" and what Bard should have done differently. Bard does not contest Dr. McMeeking's qualifications to address this topic or that the topic is relevant, limiting its challenge to reliability. As explained herein, at most, Bard's scattershot of criticisms (based primarily on distortions of Dr. McMeeking's testimony) goes to the weight rather than the admissibility of Dr. McMeeking's opinions.

Expert testimony is sufficiently reliable if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the expert has reliably applied the principles and methods to the facts of the case. Fed. R. Evid. 702. This Court has emphasized, "[i]n serving its gatekeeping function, the court must be careful not to cross over into the role of fact-finder. It is not the job of the court to insure that the evidence heard by the jury is error-free, but to insure that it is not wholly unreliable." *Long v. TRW Vehicle Safety Sys. Inc.*, 09-cv-2209, 2011 WL 5007431, at *3 (D. Ariz. Oct. 20, 2011) (quotation and citation omitted). This Court has also noted that "the 2000 amendments to Rule 702 (adopting the *Daubert* standard) 'were not intended to signal an abandonment of the liberal attitude of the Federal Rules of Evidence toward the admissibility of opinion testimony.'" *Wichansky v. Zowine*, 13-cv-1208-PHX, 2016 WL 6818945, at *3 (D. Ariz. Mar. 22, 2016) (quoting 4 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 702.05[2][a] (2d. ed. 2015)). Dr. McMeeking's opinions satisfy the reliability requirement of *Daubert* and Rule 702 because they are based on a

sound methodology that employs reason, data, and the generally accepted methods of his discipline.[4] (Ex. 1, McMeeking Dep. Tr., 304:14-305:4, July 6, 2017.)

1. Dr. McMeeking's opinions are based on reliable principles and methods applied to the facts of this case.

Dr. McMeeking's methodology includes a mechanical analysis using geometric, algebraic, and calculus methodologies with numerical computation and separately with computer techniques (Finite Element Analysis, or FEA). (Def. Ex. A, McMeeking 3/3/17 Report, at 2; Ex. 1, McMeeking Dep. Tr., 306:4-15.) These methods allow Dr. McMeeking to quantify the stress and strain on Bard's filters in order to assess the various designs and the likelihood of failure via tilt, perforation, migration, and/or fracture. In order to perform his engineering analysis, Dr. McMeeking gathered information about Bard's filters from engineering drawings and other Bard documentation; about the properties of the materials of which Bard's filters are composed (nitinol) from scientific publications; and about the *in vivo* conditions that the filters experience after implantation from Bard documentation and medical documents, including books and scientific papers, all of which is cited and explained in his report. (Def. Ex. A, McMeeking 3/3/17 Report, at 2, 11, 13.) The Bard documentation reviewed by Dr. McMeeking to perform his assessment and reach his conclusions includes:

[redacted]

[4] Dr. McMeeking's methodology, including use of Euler-Bernoulli beam theory, is set forth in the authoritative textbooks cited in his report, including texts authored by Boresi & Sidebottom and Dieter & Schmidt. Def. Ex. A, McMeeking 3/3/17 Report, at 3, 21, 81, 84; Ex. 2, Arthur P. Boresi & Omar M. Sidebottom, *Advanced Mechanics of Materials* 97 (4th ed. 1985) ("A major part of this book is concerned with (1) stress analysis, (2) the behavior of various materials subjected to stress and strain, and (3) the theoretical determination of the relationship between appropriate values of stress, strain, displacement, load, number of repetitions of load, etc. and the mode of failure."); *id.* at chs. 6, 8; Ex. 3, George E. Dieter & Linda C. Schmidt, *Engineering Design* 10 (5th ed. 2013) (1.3.3 A Problem-Solving Methodology).

[redacted]

(*Id*. at 8.) Dr. McMeeking focused on a worst-case analysis for the stresses and strains that the filters would encounter upon implantation because that should have been Bard's focus during the design process. (*Id*. at 12; Ex. 1, McMeeking Dep. Tr., 308:1-9.) Dr. McMeeking's calculations, FEA analyses and review of Bard's testing and documentation provide a more than sufficient basis for his opinions; performance of his own bench testing was not necessary,[5] nor is such testing part of his normal protocol outside of the litigation context. (Ex. 1, McMeeking Dep. Tr., 29:20-30:1; 306:16-307:2; 319:19-320:2; 334:16-335:18.)

The techniques used by Dr. McMeeking to perform his quantitative analysis are those that he teaches to undergraduate and graduate engineering students and that he uses in his consulting work for various companies, including medical-implant manufacturers. (Def. Ex. A, McMeeking 3/3/17 Report, at 2, 10.) As Dr. McMeeking has opined, had Bard engaged in this same analysis in a timely fashion as part of its design validation and verification of its devices, Bard would have been alerted to design deficiencies and failure modes that it should have immediately addressed and corrected. (*Id*. at 2-4, 10; Ex. 1, McMeeking Dep. Tr., 309:17-310:11.)

By performing his quantitative analysis, Dr. McMeeking was able to identify changes that Bard could have and should have made to its designs in order to reduce the

[5] *Quilez-Velar v. Ox Bodies, Inc*., 823 F.3d 712, 718-19 (1st Cir. 2016) (collecting cases holding that *Daubert* does not require an expert to have tested an alternative design); *Eisenbise v. Crown Equipment Corp*., No. 15-CV-0972, 2017 WL 2103559, at *5 (S.D. Cal. May 15, 2017) (whether expert mechanical engineer tested alternative design goes to the weight, not the admissibility, of his testimony); *Sahm v. STL Int'l, Inc*., No. 3:13-cv-0806, 2015 WL 1825368, at *11 n.3 (D. Or. Apr. 22, 2015) (fact that mechanical engineer "did not test the alternative designs may be a basis on which Defendants can impeach the expert testimony, but does not render the testimony inadmissible under the facts of this case."); *Hasan v. Cottrell, Inc*., No. 10 CV 5534, 2014 WL 4124254, at *4-5 (N.D. Ill. Aug. 21, 2014) (lack of testing of alternative design goes to factual underpinnings of expert testimony and is proper subject of cross-examination).

risks of tilt, perforation, migration, and fracture. These changes are set forth in his reports. For example, Dr. McMeeking identified a strain concentration where the arms enter the sheath of the G2 and G2X filters which can elevate the alternating strain and cause rapid fatigue fracture of an arm. (Def. Ex. A, McMeeking 3/3/17 Report, at 9, 12, 14, 62-64.) Dr. McMeeking opines in his report that had Bard conducted an appropriate engineering analysis focused on worst cases, it would have identified this strain concentration and should have reduced or eliminated it [redacted] (*Id*. at 12.) An appropriate analysis by Bard also would have identified the [redacted] (*Id*.)

Additional deficiencies in Bard's design process include its failure to consider the worst-case scenario when testing its designs. (*Id*. at 17, 26-28; Ex. 1, McMeeking Dep. Tr., 307:3-308:9.) Significantly, Bard's expert Dr. Paul Briant agrees that the worst-case scenario should be accounted for in the design process. (Ex. 4, Briant Dep. Tr. (July 13, 2017), 93:16-94:6; Ex. 5, Briant Dep. Tr. (Aug. 12, 2016), 14:25-15:15; 66:6-67:5; 83:9-17.) Specifically, Bard's tests did not take into account the worst-case *in vivo* conditions caused by breathing and Valsalva maneuvers (from coughing, bowel movements, etc.), which are conditions its own expert testified should be considered. (Def. Ex. A, McMeeking 3/3/17 Report, at 17, 57; Ex. 5, Briant Dep. Tr. (Aug. 12, 2016), 86:19-87:3.) Bard also made no attempt to duplicate worst-case conditions by simulating tilt, perforation, and endothelialization, all of which increase the strains on the filters. (*Id*. at 17-18, 22, 65; Ex. 6, McMeeking 4/7/17 Report, at 2-3, 5, 9; Ex. 5, Briant Dep Tr. (Aug. 12, 2016), 83:24-84:17; 87:12-18 (perforation, endothelialization, and tilting should be part of worst-case analysis.).) Most importantly, Bard's testing did not duplicate the past fatigue and other failures (including caudal migration) of Bard's filters, which would have identified the root cause of past deficient performances. (Def. Ex. A, McMeeking 3/3/17 Report, at 17-19, 22, 24.) [redacted]

[redacted] (*Id.* at 17.)

2. Bard's Motion cherry picks and distorts Dr. McMeeking's opinions, testimony, and statements.

Instead of addressing the detailed analysis in Dr. McMeeking's reports, Bard has cherry-picked quotes from his deposition that are out of context and misleading. Bard begins this selective analysis with the false statement that "Dr. McMeeking admits he has used no research, no testing, or any sort of accepted scientific methodology to determine what was reasonably practicable for Bard to have done in order to reduce risks associated with its IVC filters, and, at best, relies on Dr. Ritchie to provide any basis for these opinions." (Mot. at 4-5.) Nothing could be further from the truth. Dr. McMeeking made no such statement,[6] and the quantitative engineering analysis set forth in Dr. McMeeking's expert reports is an accepted methodology in his field to address stresses and strains in the design process. (Ex. 1, McMeeking Dep. Tr., 304:14-305:4.) Dr. McMeeking deferred to Dr. Ritchie on the timing of electropolishing, not generally on what Bard could have done to reduce risks. (Ex. 1, McMeeking Dep. Tr., 30:7-15; 31:21-32:4.) With respect to electropolishing, which Bard first used with the Eclipse filter, Dr. McMeeking very clearly explained the flaw in Bard's approach to the design process, namely its failure to identify the root cause of fractures:

[redacted]

[6] Dr. McMeeking never stated that he did no research or investigation, or that he employed no accepted scientific methodology, to address what Bard could have done to reduce the risks in its filters. As explained in this response, Dr. McMeeking's reports lay out his research, investigation and methodology used to address the flaws in Bard's designs and what Bard should have done to identify and correct them.

(Def. Ex. A, McMeeking 3/3/17 Report, at 15 (emphasis added).)

Bard continues its cherry-picking by criticizing Dr. McMeeking for not identifying other filter manufacturers who made specific changes, such as the addition of anchors or limiters, sooner than Bard did. (Mot. at 5.) But whether an expert has identified others who have made a proposed design change is not a basis for exclusion. *Eisenbise*, 2017 WL 2103559, at *6. In any event, Dr. McMeeking has repeatedly explained how, if Bard had followed the proper design protocols, it would have identified the defects in its design such that it could have corrected them sooner, regardless of what its competitors were doing. (*E.g.*, Ex. 1, McMeeking Dep. Tr., 309:17-310:11.) Further, Bard again ignores Dr. McMeeking's report, in which he provides an in-depth analysis of Bard's caudal anchors, explaining that they are flawed because Bard's own test results demonstrate that its anchors were unable to eliminate or reduce the tendency to tilt. (Def. Ex. A, McMeeking 3/3/17 Report, at 18-19.) This is significant, according to Dr. McMeeking, because tilting is enabled by caudal motion, and properly designed caudal anchors should be able to arrest tilt. (*Id.*)

Bard continues with its false accusations, stating that Dr. McMeeking "does not even have an opinion whether the anchors or limiters on Bard's Meridian or Denali filter models would improve resistance to migration, tilt, perforation or fracture" and that Dr. McMeeking had done no work "to determine whether these design changes would have reduced these risks." (Mot. at 5.) In fact, Dr. McMeeking did state, in the very quote cited by Bard, that to the extent they limit tilt and migration, caudal anchors would have beneficial effects on perforation and fracture. (Ex. 1, McMeeking Dep. Tr., 130:6-19; *see also* 132:23-133:1 [redacted].) But, as Dr. McMeeking explained in his report, Bard's testing shows that its caudal anchors are not effective and do not prevent tilt. (Def. Ex. A, McMeeking 3/3/17 Report, at 18-19, 22-24.) Bard's accusations to the contrary, Dr. McMeeking has in fact done work to determine whether Bard's design changes reduce risks – by reviewing Bard's test results and conducting his own engineering analysis.

Next, Bard falsely states that Dr. McMeeking "admits that he has not specifically examined in Bard filters how changes to the type of material used, diameter of limbs, shapes of limbs, and numbers of limbs would cause Bard's filters to perform better." In fact, when he was asked that *exact question* at deposition, Dr. McMeeking responded: [redacted] (Ex. 1, McMeeking Dep. Tr., 35:15-25.) Thus, Dr. McMeeking did *not* say he had not done this work; he said he *did* do it.[7] In his Rebuttal Report, Dr. McMeeking compares the Simon Nitinol Filter to Bard's later filters, and explains at length why the design features of the Simon Nitinol filter allow it to perform better with respect to tilt, perforation, migration, and fracture. (Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 12-16 (discussing design changes that could have been made to the Recovery and G2 filters that would have recaptured some of the beneficial aspects of the SNF filter design); *see also* Ex. 1, McMeeking Dep. Tr., 203:23-205:24; 211:5-25.)

3. Bard ignores Dr. McMeeking's actual opinions regarding the Denali.

Bard's criticisms of Dr. McMeeking's opinions about the Denali filter ignore Dr. McMeeking's reports. (Mot. at 6.) Although the Denali's design eliminates one strain concentration, Dr. McMeeking determined that the design introduces a different strain concentration where the limbs merge into the tubular cap of the filter. (Def. Ex. A, McMeeking 3/3/17 Report, at 20-21.) Dr. McMeeking also noted additional design deficiencies of the Denali, including that the arms do not have penetration limiters, and the penetration limiters on the legs "are very small and will have little effect on inhibiting the legs penetrating and perforating the vena cava wall." (*Id*. at 23; *see also* Ex. 1, McMeeking Dep. Tr., 310:18-311:7.) Thus, contrary to Bard's assertions, Dr. McMeeking did state a basis for his opinion that Bard failed to reduce the risks in the Denali as far as reasonably practicable.

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[7] *See also* Def. Ex. A, McMeeking 3/3/17 Report, at 53 (Dr. McMeeking's engineering analysis shows that [redacted]

4. Dr. McMeeking's opinions are admissible.

In summary, Dr. McMeeking has offered opinions regarding the methods that Bard should have employed, and specific changes that Bard should have made, in order to reduce the risk that its filters would tilt, perforate the IVC, migrate, and fracture. Dr. McMeeking bases his opinion regarding these suggested design changes on his calculations and FEA analyses, along with his review of Bard's testing data, FEA analyses, and other engineering documents. In the context of an engineer's evaluation of alternative design, the use of mathematical calculations like those of Dr. McMeeking "is a perfectly acceptable form of test." *Lapsley v. Xtek, Inc*., 689 F.3d 802, 815 (7th Cir. 2012).[8] Stress calculations and review of data are also a sufficient basis for an alternative design opinion. *Quilez-Velar*, 823 F.3d at 718-19. Dr. McMeeking applied a reliable methodology to the facts and data pertinent to this case, and he should therefore be permitted to testify.

B. Dr. McMeeking Should be Permitted to Offer the Limited Opinions in his Reports Regarding Bard's Communication Failures with the FDA.

Consistent with his report, Dr. McMeeking testified at his deposition that he will offer targeted opinions regarding Bard's communications with the FDA. Dr. McMeeking explained that he will not offer the opinion at trial that Bard complied or failed to comply with any particular FDA regulations. (Ex. 1, McMeeking Dep. Tr., 51:20-23; 175:5-11.) Rather, as stated in his report and at his deposition, Dr. McMeeking will testify that Bard presented specific misleading information to the FDA, and that Bard was not frank and honest with the FDA. For these opinions, Dr. McMeeking relies on his own engineering assessment of Bard's statements to the FDA regarding the fatigue behavior of the G2 filter. (Ex. 1, McMeeking Dep. Tr., 52:21-54:2; 54:19-55:6; Def. Ex. A, McMeeking

[8] *See also* Ex. 4, Briant Dep. Tr. (July 13, 2017), 95:17-96:8; 96:18-23 (Bard's expert Dr. Briant testifies use of FEA is an appropriate, well-recognized methodology within the engineering field to calculate strains); *Baugh v. Cuprum S.A. de C.V.*, 845 F.3d 838, 844-45 (7th Cir. 2017) (rejecting the contention that the engineer should have tested a physical exemplar, noting that the expert "*did* test his alternative design, using centuries-old mathematics principles.") (emphasis added).

3/3/17 Report, at 67.) Dr. McMeeking explained that Bard's representation to the FDA that the G2 is twelve times better than the Recovery in terms of its fatigue performance is incorrect and misleading. (Ex. 1, McMeeking Dep. Tr., 52:21-54:2; 54:19-55:6; Def. Ex. A, McMeeking 3/3/17 Report, at 29.) Dr. McMeeking further noted that information Bard provided to the FDA in a 510(k) submission for the G2 filter was misleading [redacted] (Def. Ex. A, McMeeking 3/3/17 Report, at 67.)

Dr. McMeeking will also testify that Bard [redacted] (Def. Ex. A, McMeeking 3/3/17 Report, at 16.) Likewise, Dr. McMeeking will testify that Bard [redacted] and that Bard [redacted] (*Id*. at 20 & 25.) With respect to these opinions, Dr. McMeeking relies upon and incorporates the opinions of Dr. Parisian regarding Bard's communications with the FDA. (Ex. 1, McMeeking Dep. Tr., 51:24-52:8; 54:8-16; Def. Ex. A, McMeeking 3/3/17 Report, at 10, 16, 20, 25.)

Dr. McMeeking's opinions regarding Bard's communication failures with the FDA are relevant and reliable, and he is qualified to make them.[9] As set forth in part II, *supra*, Dr. McMeeking has appeared both formally and informally before the FDA on behalf of

[9] *See Smith v. Ford Motor Co.*, 215 F.3d 713, 721 (7th Cir. 2000) ("[A] court should consider a proposed expert's full range of practical experience as well as academic or technical training when determining whether that expert is qualified to render an opinion in a given area.").

medical device companies to provide his engineering assessments of biomedical implants, including issues pertaining to *in vivo* loading, stress/strain analysis, fatigue, fracture, stability and durability. (Def. Ex. A, McMeeking 3/3/17 Report, at 1-2.) Bard does not challenge Dr. McMeeking's qualifications to provide opinions regarding incorrect information provided by Bard to the FDA "with respect to particular documents." (Mot. at 7.) Nor does Bard challenge the relevance or reliability of Dr. McMeeking's opinions regarding the specific incorrect and misleading statements Bard made to the FDA "with respect to particular documents." Rather, Bard appears to limit its challenge to Dr. McMeeking's reliance on Dr. Parisian. However, an expert's opinions may be based upon "the reliable opinions of other experts." Fed. R. Evid. 702 Advisory Committee's note (2000 Amendments).[10] *See also* Plaintiffs' Omnibus Mem., at Section II.B. Thus, in addition to reaching his own conclusion regarding Bard's misleading statements to the FDA, Dr. McMeeking independently relies on Dr. Parisian's analysis of Bard's dealings with the FDA, and he should be permitted to base his opinion on both.

C. Dr. McMeeking Should be Permitted to Offer the Limited Opinions in his Reports Regarding the Rates of Complications of Bard's Filters.

Bard contends that Dr. McMeeking should not be permitted to "opine that rates of complications in Bard filters are 'dangerous.'" (Mot. at 9.) But, actually, Bard challenges Dr. McMeeking's right to testify regarding the rates at which Bard's devices fail. (*Id.* at 9-11.) Dr. McMeeking has reviewed and relies upon Bard's and Dr. Betensky's analyses of rates of complications of Bard's filters for the limited purpose of confirming that these data are consistent with his engineering analyses. Dr. McMeeking does not claim to be a medical doctor or a statistician, and for this reason he will not testify that the complication

[10] In response to *Daubert*, the Advisory Committee amended Rule 702 in 2000, and explained in pertinent part: "The amendment requires that expert testimony be based on sufficient underlying 'facts or data.' The term 'data' is intended to encompass the reliable opinions of other experts."

rates are dangerous. Dr. McMeeking simply uses the rates as one of several measures to ensure that his methodology is reliable,[11] which is permissible under *Daubert*.

Dr. McMeeking relies on Dr. Betensky's report as confirmation that the rates of failure of the SNF versus other Bard filters are consistent with his engineering analysis. (Ex. 1, McMeeking Dep. Tr., 189:10-23; *see also* Def. Ex. A, McMeeking 3/3/17 Report, at 25-26 [redacted].) Similarly, Dr. McMeeking relies on Bard's analyses of failure rates to confirm the results of his engineering analyses. (*E.g.*, Def. Ex. A, McMeeking 3/3/17 Report, at 15-16 (regarding marginal improvement of rate of fracture of Eclipse as compared to G2); Ex. 6, McMeeking 4/7/17 Report, at 7-8 (Bard's data on Meridian's failure rate [redacted].) As explained in Section II.B of Plaintiffs' Omnibus Memorandum, it is appropriate for experts to rely on the reports of other experts for background and data, which is what Dr. McMeeking is doing here. *See also* note 10 *supra*.

D. Dr. McMeeking Should be Permitted to Testify that the Simon Nitinol Filter is Substantially Less Likely to Result in Complications as Compared to Bard's Other Filters.

Finally, Bard contends that Dr. McMeeking should not be allowed to opine that Bard's own Simon Nitinol filter is a safer alternative product. (Mot. at 11.) Based on his comprehensive engineering analysis of Bard's filters, which is detailed at length in his reports, Dr. McMeeking concluded:

[redacted]

[11] Additional verifications and validations include Dr. McMeeking's comparison of his beam bending calculations with his computer-generated FEA results, which demonstrates that his calculations are "remarkably accurate." Def. Ex. A, McMeeking 3/3/17 Report, at 55. Dr. McMeeking also compared his FEA results with those of Bard's expert Dr. Paul Briant, and found that "my results are always consistent with his results in terms of the magnitude of the strains which are predicted." Ex. 1, McMeeking Dep. Tr., 87:19-88:5.

[redacted]

(Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 16.) Because Dr. McMeeking is qualified to offer an opinion comparing the safety of designs from an engineer's perspective, and because his opinion is both relevant and reliable, Dr. McMeeking should be permitted to offer this opinion at trial.

Defendants' case law, which applies the law of New York,[12] is inapposite. In both cases cited by Bard, the aspect of the product that caused the alleged defect was necessary to make the product function as intended. In *McCarthy*, the court found that the bullets at issue were intended to be particularly dangerous, and that they performed as intended.[13] In *Felix*, the court held that the solvent in the sealer was required in order for the product to function as intended.[14] In contrast, with respect to the five bellwether plaintiffs at issue, and the thousands of other plaintiffs in this MDL, Bard's filters did not perform as intended. The bullets in *McCarthy* were supposed to injure the victims the way they did, but Bard's filters were not supposed to tilt, perforate the IVC, fracture, or migrate. And it is not the retrievability aspect of Bard's post-Simon Nitinol filters that caused them to tilt, perforate, fracture, or migrate.[15] Rather, as Dr. McMeeking has explained at length in his

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[12] New York law does not apply to any of the bellwether cases.

[13] *McMarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997) ("The very purpose of the Black Talon bullet is to kill or cause severe wounding. Here, plaintiffs concede that the Black Talons performed precisely as intended by the manufacturer.").

[14] *Felix v. Akzo Nobel Coatings, Inc.*, 262 A.D.2d 447, 692 N.Y.S.2d 413 (2d Dept. 1999) (holding that "there was no competent evidence set forth by the plaintiff that there was an alternative, safer design and the evidence clearly indicates that the volatile solvent contained in the defendant's quick-drying lacquer sealer is critical to the products' performance.").

[15] Unlike *McCarthy* and *Felix*, the safer alternative design here (the Simon Nitinol filter) is the predicate device used by Bard to obtain 510(k) clearance of all of Bard's subsequent filters. As required, therefore, Bard represented to the FDA that each of its filters is substantially equivalent to the Simon Nitinol in terms of both safety and effectiveness. *See infra* note 19 (identifying predicate devices Bard represented to the FDA as substantially equivalent to the Recovery, G2, G2 Express, Eclipse, Meridian, and Denali filters). If making the Recovery, G2, and later filters retrievable also made them less safe in terms of tilt, perforation, migration, and fracture as compared to the Simon Nitinol filter, then it was not appropriate for Bard to use the Simon Nitinol as a predicate device.

reports, the problem with these filters is their defective design. (*E.g.*, Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 8-16.)

Bard's criticism of Dr. McMeeking's safer-alternative-design opinion is a classic example of an inappropriate use of *Daubert*. To the extent Bard believes that Dr. McMeeking did not consider certain benefits (*e.g.*, retrievability) of Bard's filters in reaching his opinions, that is fodder for cross-examination but is not a basis for exclusion. *See City of Pomona v. SQM North Am. Corp.*, 750 F.3d 1036, 1049 (9th Cir. 2014) ("Even if [expert's] conclusions were 'shaky,' they should be attacked by 'cross examination, contrary evidence, and attention to the burden of proof, not exclusion.'") (cit. om.). Key to the *Daubert* analysis is that Dr. McMeeking employed a reliable, well-accepted methodology – mathematical calculations along with review of Bard's documentation – to reach his conclusions.[16] Indeed, Bard does not contest Dr. McMeeking's methods, but has instead focused on his conclusions,[17] which is not an appropriate *Daubert* challenge. *Daubert*, 509 U.S. at 595 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.").

Citing another New York case,[18] Bard argues that Dr. McMeeking should not be permitted to rely on Dr. Betensky's opinions regarding the relative rates of complications

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See, e.g., Ex. 7, Brauer Dep. Tr., 92:18-23, May 23, 2014 (Bard's expert opining that "If, hypothetically speaking, the Recovery filter was shown to no longer be substantially equivalent to its predicate device, hypothetically speaking, then hypothetically speaking it would not be an appropriate predicate device for G2.").

[16] *E.g.*, *Baugh*, 845 F.3d at 843-45 (mechanical engineer's alternative design methodology was reliable where the engineer tested the design by performing hand-written calculations); *Quilez-Velar*, 823 F.3d at 718-19 (mechanical engineer's calculations along with review of data was sufficient basis for alternative design opinion); *Lapsley*, 689 F.3d at 815 (use of a mathematical model to assess design is "a perfectly acceptable form of test.").

[17] Mot. at 12 (conceding that Dr. McMeeking is capable of evaluating the design characteristics of an implantable medical device, but complaining about his conclusion that the SNF is a superior design as compared to other Bard filters).

[18] *Barban v. Rheem Textile Sys., Inc.*, No. 01-CV-8475, 2005 WL 387660 (E.D.N.Y. Feb. 11, 2005). It is not clear whether Bard intended to cite this case. Bard's parenthetical for this case, Mot. at 12-13, describes expert testimony related to a "table saw," but the

of Bard's filters. Bard has misstated Dr. McMeeking's opinions. Dr. McMeeking did not reference Dr. Betensky's opinions or report in his analysis of the SNF as a safer alternative design. (Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 8-16.) In fact, Dr. McMeeking began his SNF analysis with a statement making it clear that his opinion is based on an engineering methodology, *not* on comparison of rates:

[redacted]

(Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 8 (emphasis added).) Unlike the expert in *Barban*, Dr. McMeeking has conducted a thorough engineering analysis to reach his opinions on alternative design, independent of evidence regarding rates. At his deposition, Dr. McMeeking explained that at most, he is relying on Dr. Betensky's report as confirmation that the rates of failure of the SNF versus other Bard filters are consistent with his engineering analysis. (Ex. 1, McMeeking Dep. Tr., 189:10-23; *see also* Def. Ex. A, McMeeking 3/3/17 Report, at 25-26.) In any event, an expert may adopt and incorporate opinions of other experts. *See* Plaintiffs' Omnibus Mem., at Section II.B.

Bard further argues that the SNF cannot be a safer alternative design for its optionally retrievable filters because it is functionally different – i.e., permanent only versus an option for retrieval. Nothing could be further from the truth. Bard chose to rely on the SNF as the predicate device for its optionally retrievable filters, which requires those filters to be "substantially equivalent" to the SNF.[19] Bard then made the choice to

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Barban case is about a laundry press machine used to press clothing at a dry cleaning business.

[19] For a medical device to be cleared by the FDA through the 510(k) process, a premarket submission must be made to the FDA to demonstrate that the device sought to be cleared is substantially equivalent to an already legally marketed device. *See* 21 C.F.R. § 807.92(a)(3).

Each clearance of Bard's retrievable filters ultimately traces back to the SNF:

have two of its filters, the Recovery and G2, initially cleared for permanent only use – just like the SNF. (*See* Ex. 19, 510(k) Summary K022236, *supra* note 19; Ex. 17, 510(k) Summary K050558, *supra* note 19.) Those same filters, with no change, were then cleared for optional retrieval. (*See* Ex. 18, 510(k) Summary K031328, *supra* note 19; Ex. 14, 510(k) Summary K073090, *supra* note 19.) But Bard did not stop there, as it has

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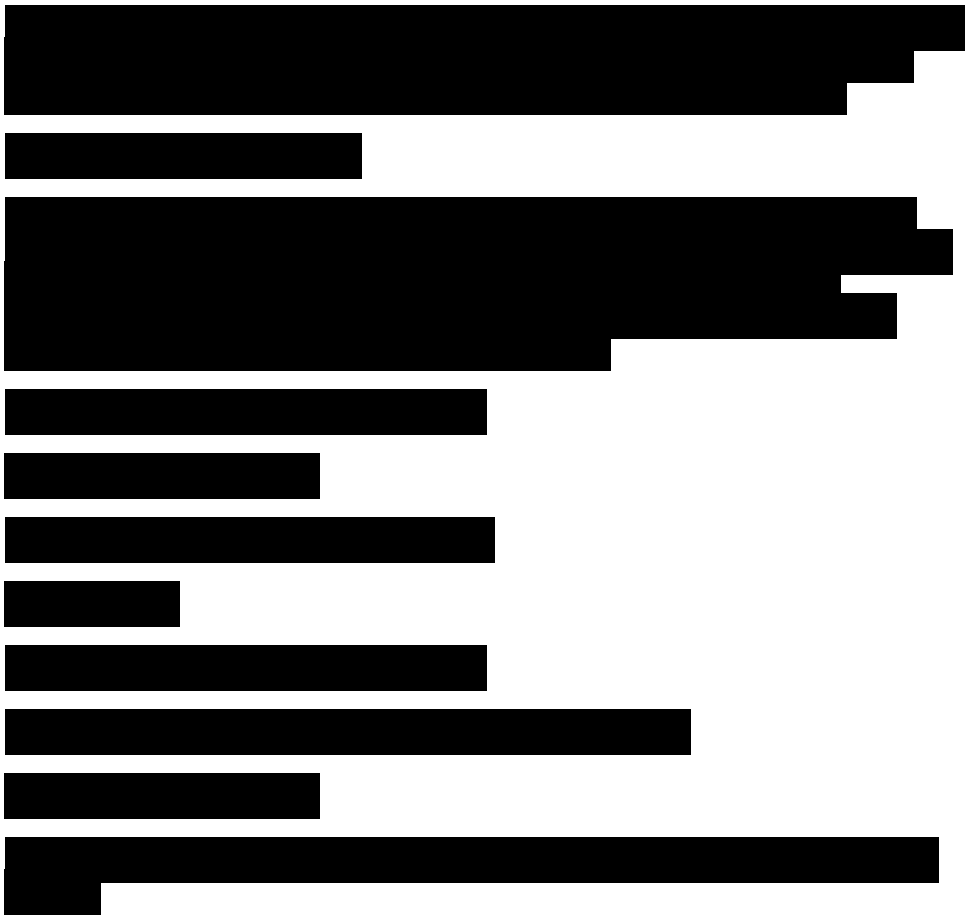
- The predicate device for both the Denali retrievable filter (K130366) and the Meridian retrievable filter (K102511) is the Eclipse retrievable filter (K101431). *See* Ex. 8, 510(k) Summary K130366 (May 15, 2013), https://www.accessdata.fda.gov/cdrh_docs/pdf13/K130366.pdf; Ex. 9, 510(k) Summary K102511 (Aug. 24, 2011), https://www.accessdata.fda.gov/cdrh_docs/pdf10/K102511.pdf.
- The predicate device for the Eclipse retrievable filter (K101431) is an earlier version of the Eclipse retrievable filter (K093659). *See* Ex. 10, 510(k) Summary K101431 (June 25, 2010), https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101431.pdf.
- The predicate device for the earlier Eclipse retrievable filter (K093659) is the G2 Express retrievable filter (K082305). *See* Ex. 11, 510(k) Summary K093659 (June 14, 2010), https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093659.pdf.
- The predicate device for the G2 Express retrievable filter (K082305) is an earlier version of the G2 Express retrievable filter (K080668). *See* Ex. 12, 510(k) Summary K082305 (Oct. 31, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf8/K082305.pdf.
- The predicate device for the earlier G2 Express retrievable filter (K080668) is the G2 retrievable filter (K073090). *See* Ex. 13, 510(k) Summary K080668 (July 30, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf8/K080668.pdf.
- The predicate devices for the G2 retrievable filter (K073090) are two versions of the G2 permanent filter: femoral approach (K062887) and jugular/subclavian approach (K052578). *See* Ex. 14, 510(k) Summary K073090 (Jan. 15, 2008), https://www.accessdata.fda.gov/cdrh_docs/pdf7/K073090.pdf.
- The predicate device for both the femoral and jugular/subclavian G2 permanent filters (K062887 & K052578) is an earlier version of the G2 permanent filter (K050558). *See* Ex. 15, 510(k) Summary K062887 (Oct. 26, 2006), https://www.accessdata.fda.gov/cdrh_docs/pdf6/K062887.pdf; Ex. 16, 510(k) Summary K052578 (Nov. 25, 2005), https://www.accessdata.fda.gov/cdrh_docs/pdf5/K052578.pdf.
- The predicate device for both the earlier G2 permanent filter (K050558) and the Recovery retrievable filter (K031328) is the Recovery permanent filter (K022236). *See* Ex. 17, 510(k) Summary K050558 (Aug. 29, 2005), https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050558.pdf; Ex. 18, 510(k) Summary K031328 (July 25, 2003), https://www.accessdata.fda.gov/cdrh_docs/pdf3/K031328.pdf.
- The predicate device for the Recovery permanent filter (K022236) is the **Simon Nitinol filter**. *See* Ex. 19, 510(k) Summary K022236 (Nov. 27, 2002), https://www.accessdata.fda.gov/cdrh_docs/pdf2/K022236.pdf.

continued to represent and market its optionally retrievable filters as permanent filters that "may" be retrieved. For example:

- Bard's marketing brochure for the Recovery filter represents it is "Designed to be the only filter you will ever need" and "the permanent solution for caval interruption." (Ex. 20, BPV-17-01-00007760, at 7760–7761);
- Bard's marketing brochure for the G2 filter for permanent use refers to it as a "permanent filter platform". (Ex. 21, BPV-17-01-00142912, at 142913);
- The Instructions for Use ("IFU") for the Eclipse Filter specifically state (as do all of the IFUs for Bard's optionally retrievable filters) that "The Eclipse Filter is designed to act as a permanent filter." (Ex. 22, BPVE-01-01081046, at 1081048).

Bard's own expert witness, vascular surgeon Mark Moritz, M.D., confirmed Bard's optionally retrievable filters are marketed as permanent filters and should behave the same as the predicate device, the SNF:



[redacted]

(Ex. 23, Moritz Dep. Tr., 68:21-70:15, July 18, 2017.) He further testified:

[redacted]

(*Id.* at 72:10-14.) Bard's misleading assertion that the SNF is functionally different from its optionally retrievable filters (Recovery, G2, G2X, Eclipse, Meridian, and Denali) is contrary to its own representations and actions, the testimony of its own medical expert, and the evidence in this litigation. Bard's Rule 403 argument is therefore baseless and should be rejected.

Bard next argues Dr. McMeeking should not be permitted to offer the medical opinion that any specific patient should have received an SNF instead of the filter actually received. (Mot. at 13.) However, Bard misconstrues and attempts to twist the opinion that Dr. McMeeking is giving. Dr. McMeeking has offered a general opinion from an engineering perspective that the SNF has a substantially better design than Bard's other filters because it performs better with respect to tilt, perforation, migration, and fracture. (Def. Ex. E, McMeeking 5/11/17 Rebuttal Report, at 8-16.) As an engineer, he is more than qualified to opine as to the design problems with the specific filter received by each of the bellwether plaintiffs,[20] how those design shortcomings led to the failure of those

[20] Dr. McMeeking wrote case-specific expert reports for each of the five bellwether plaintiffs, which were not challenged (or even mentioned) in Bard's *Daubert* motion.

devices that ultimately manifested, and why the design of the SNF, or specific features thereof, is safer and better. Dr. McMeeking is not a medical doctor and is not offering an opinion as to which particular filter – whether a permanent filter, another optional filter, no filter, or otherwise – should have been used for each of the specific bellwether plaintiffs. Simply put, Dr. McMeeking is opining as to safer-alternative-design options for Bard's optional filters, not as to the medical decision of which filter should have been used or if a filter even should have been used.

Lastly, there is no question that Dr. McMeeking's opinion that the SNF is a better, safer design is relevant to the bellwether cases.[21] Under Rule 702, expert testimony need only be relevant to an issue in the case; it need not relate directly to the ultimate issue. *Messick v. Novartis*, 747 F.3d 1193, 1196 (9th Cir. 2014) ("The relevancy bar is low, demanding only that the evidence 'logically advances a material aspect of the proposing party's case.'") (cit. om.). Each of the bellwether plaintiffs was injured by the failure and subpar performance of a Bard IVC filter, and the existence of a safer design option for these filters is directly relevant to the jury's ultimate decision. Because Dr. McMeeking's opinions regarding the flaws in Bard's post-SNF filter designs, and the existence of a safer, better design, will be helpful to the jury in reaching its decision regarding design defect, he should be permitted to offer them.

IV. CONCLUSION

For the reasons stated herein, Plaintiffs request that the Court deny in full Bard's Motion to exclude the expert opinions of Dr. Robert McMeeking.

[21] For example, under pertinent state law, evidence of safer alternative design is allowed but not required for several bellwether plaintiffs. *Rahmig v. Mosley Mach. Co.*, 412 N.W.2d 56, 78-82 (Neb. 1987) (relevant to Kruse); *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 674 (Ga. 1994) (relevant to Jones and Booker).

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti